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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RU, POWEN

ART UNIT

PAPER NUMBER

2194

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/502,096		NORGAARD ET AL.	
	Examiner		Art Unit	
	Powen Ru		2194	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/22/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-16 and 21 is/are rejected.
- 7) ☒ Claim(s) 9-10 and 17-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20040722</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This is the initial office action based on the application filed on 7/22/2004. Claims 1-21 are currently pending and have been considered below.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "21" (Fig. 4) has been used to designate both a wax retaining barrier and an outwardly oriented flange (12 in Fig. 2). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 8a (Fig. 2). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid

abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to as failing to comply with 37 CFR 1.72(a), because it exceeds 150 words in length (153 words). Besides, there are two typographical errors: "etend" (line 6) and "accomodating" (line 7). The Examiner assumes they are "extend" and "accommodating" respectively. Correction is required. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. Correction is required.

4. The disclosure is objected to because of the following informalities:

- Page 1 line14: "stile" should be "style".
- Page 2 line 8: "draw back" should be "drawback".
- Page 2 lines 9-10: " - - exerting to high a force - - " is not clear.
- Page 3 line 10: "an" should be "and".

- Page 5 lines 24-26: “both to produce - - and it aids the tools to obtain - - ”, the underlined phrase seems redundant.
- Page 8 lines 29-30: “se” should be “see” (two occurrences).

The Examiner notices that there are numerous errors in the specification. But it must be remembered that an examination is not made for the purpose of securing grammatical perfection. The Applicant should revise the specification carefully. Appropriate correction is required.

5. The specification is objected to as improperly citing claim numbers: claims 1-6 (Page 5 line 32). As the claim numbers are subject to reordering after prosecution, merely citing claim numbers in the specification may lead to confusion. The Applicant should recite the necessary text from the cited claims to ensure the clarity of the disclosure. Appropriate correction is required.

Claim Objections

6. Claims 1, 8, and 15: Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation to comply with 37 CFR 1.75(i).

7. Claim 10 is objected to because of inconsistent terminology. The gripping flange (22) is inconsistent with the inwardly extending flange (22) of Claim 8. The Examiner will

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assume this gripping flange (22) is the inwardly extending flange (22) as in Claim 8.

Appropriate correction is required.

8. Claims 11-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The base claim is about a filter manipulator, but the "holder" in the dependent claims does not further limit the "filter manipulator" either functionally or structurally.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 7 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, depending upon Claim 1, recites the limitation "the blade parts" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The Examiner considers that Claim 7 should be dependent upon Claim 6 that discloses two opposed blade parts.

Claim 21, depending upon Claim 19, recites the limitation "the U-shaped cut-out" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The

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Examiner considers that Claim 21 could be dependent upon Claim 17 or Claim 18 that discloses the U-shaped cut-out.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Gunnensen et al. (6,795,562).

Claim 1 (as broadly claimed): Gunnensen et al discloses a filter manipulator (ear wax guard applicator 14, e.g., col 5 lines 1-13) comprising a gripping part (intermediate piece 20, col 5 lines 5-15), a first tool part (cylindrical portion 15 with cylindrical pin 23, e.g., col 5 lines 14-18) extending from the gripping part for holding and releasing a new filter (insertion of the earwax guard, e.g., col 5 lines 14-18), and a second tool part (wedge-shaped portion 16 with harpoon-shaped pressing-in peak 24, e.g., col 5 lines 4-6 and 18-24) is arranged adjacent (e.g., col 5 line 11) to the first tool part and adapted to receive and hold a used filter (removal of the earwax guard, e.g., col 5 lines 18-24).

Claim 3: Gunnensen et al discloses a filter manipulator as in Claim 1; and further discloses that the second tool part comprising a protruding part (wedge-shaped port 16, e.g., col 5 lines 1-7) extending from an edge portion (end edge surface 19, e.g., col 5 lines 18-24) of the gripping part with an outwardly extending flange (harpoon shaped pressing-in peak 24, e.g., col 5 lines 18-24).

Claim 4: Gunnensen et al discloses a filter manipulator as in Claim 3; and further discloses that the outwardly extending flange comprising a surface (catch edge 25, e.g., col 5 lines 18-24) facing the an edge portion of the gripping part and the surface extend essentially perpendicular (see Fig. 6) to the length axis of the protruding part.

Claim 5: Gunnensen et al discloses a filter manipulator as in Claim 3; and further discloses that the protruding part sectioned into two or more independent sections (e.g., wedge-shaped port 16 and harpoon shaped pressing-in peak 24, see Fig. 6) with slots of free space (e.g., space between end edge surface 19 and catch edge 25, see Fig. 6) between the sections.

13. Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Voroba (5,199,565).

Claim 11: Voroba discloses a holder (battery dispensing and removal apparatus, for hearing aid, see Fig. 1 and 6) with a number of pockets (e.g., battery dispensing station 70, col 5 lines 15-24). The Examiner notices that the Applicant claims a holder for filter manipulators in the preamble. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention

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and the prior art in order to patentably distinguish the claimed invention from the prior art (see MPEP 7.37.09). Therefore, the Examiner does not consider these intended uses in determining the patentability of the claim. The Examiner also notices that the Applicant uses clauses like "shaped to ...", "accessible for ...", and "accommodated within ..." to describe the structure of the holder. The Applicant should add more structural limitations to distinguish the invention from the prior art.

Claim 12: As the phrase "means for" is used, modified with functional language, without sufficient structure disclosed, Claim 12 will be treated under 35 U.S.C. 112, sixth paragraph. The limitation "engagement means" will be construed as the "any frictional engagement" described in the specification (e.g., page 6 lines 7-10). Voroba discloses a holder as in Claim 11; and further discloses an engagement means (holding pad 75, e.g., col 5 lines 30-35) providing the tension necessary to hold the small part in place.

Claim 13: Voroba discloses a holder as in Claim 11; and further discloses a center part (central core, e.g., col 5 lines 15-24), with pockets arranged to extend radially away from the center part (see Fig. 1 and 6).

Claim 14: Voroba discloses a holder as in Claim 13; and further discloses that the pockets are arranged flat in one and the same plane (see Fig. 1 and 6).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunnensen et al. (6,795,562) in view of Patel et al. (6,682,534).

Claim 2 (as broadly claimed): Gunnensen et al discloses a filter manipulator as in Claim 1; but does not disclose that two tool parts are arranged along one and the same edge part of the gripping part. However, Patel et al discloses a surgical instrument comprising a gripping part (proximal end 70, e.g., col 4 lines 11-15); a first tool part (first opposed member 74A, e.g., col 4 lines 30-35) extending from the gripping part (see Fig. 2); and a second tool part (second opposed member 74B, e.g., col 4 lines 30-35) is arranged adjacent (see Fig. 2) to the first tool as in Claim 1; and further discloses the two tool parts are arranged side by side along one and the same edge part (distal surface 84, e.g., col 5 lines 9-12) of the gripping part. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange adjacent tools side by side along the same edge part. As arranging two tools at the same side enables the different operations without turning the tools around, one would have been motivated to choose the structure suggested by Patel et al to modify the filter manipulator disclosed by Gunnensen et al to offer more convenience to hearing aid users. The Examiner notices that “for extraction/insertion”, “to be gripped/held”, “for holding/releasing”, “adapted to receive/hold” and “in order to extract” phrases appearing in the base claim (Claim 1). “While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d

1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)” (see MPEP 2114). Thus the Examiner does not consider that the above “intended uses” limit the claim.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunnensen et al. (6,795,562) in view of Muromoto (6,079,296).

Claim 6: Gunnensen et al discloses a filter manipulator as in Claim 1; but does not disclose the blade parts. However, Muromoto discloses an electrical wire cover peeling tool with two opposed blades (8 and 9, e.g., col 3 lines 9-15, see Fig. 7-9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use blades to remove unwanted parts. With the additional blades, the manipulator will grip and hold a filter at the external circumference thereof. One would have been motivated to add the blades suggested by Muromoto to the filter manipulator disclosed by Gunnensen et al as an alternative or additional means to extract the filter from the vent or sound outlet opening of a hearing aid.

17. Claim 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunnensen et al. (6,795,562) in view of Oliveira et al. (6,310,961) and Danielsen (5,293,008).

Claim 8: Gunnensen et al discloses an ear wax filter (ear wax guard 6, e.g., col 4 lines 28-32) comprising a tubular element (7, e.g., col 4 lines 28-32) adapted to the mouth diameter of the acoustic passage (outlet canal 4, e.g., col 4 lines 28-32), an ear wax retaining barrier (9, e.g., col 4 lines 33-39), and an outwardly extending flange (abutment collar 11, e.g., col 4 lines 39-45); but does not disclose that the filter is made

of a rigid material. However, Oliveira et al. discloses ear wax filters (cerumen guards, e.g., col 1 lines 48-54) are moldings of rigid material (e.g., stiff polymeric material, col 1 lines 48-54). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use rigid material to make earwax filters.

Moreover, Danielsen discloses that the ear wax filter may be manufactured from any suitable material known to persons skilled in this art (col 4 lines 28-30). One would have been motivated to choose rigid material suggested by Oliveira et al. to make the wax filters disclosed by Gunnersen et al. The Examiner further notices that the prior art of record does not teach or render obvious the limitation: "an inwardly extending flange". But the claim is written in such an alternative form (and/or) that does not actually limit the scope of the claim.

18. Claim 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunnersen et al. (6,795,562) in view of Voroba (5,199,565)

Claim 15 (as broadly claimed): Gunnersen et al discloses a hearing aid system comprising at least a filter manipulator (ear wax guard applicator 14, e.g., col 5 lines 1-13) having a first tool part (cylindrical portion 15 with cylindrical pin 23, e.g., col 5 lines 14-18) for initially holding and subsequently releasing a new filter (insertion of the earwax guard, e.g., col 5 lines 14-18), a second tool part (wedge-shaped portion 16 with harpoon-shaped pressing-in peak 24, e.g., col 5 lines 4-6 and 18-24) adapted to receive and hold a used filter (removal of the earwax guard, e.g., col 5 lines 20-25), and a gripping part (intermediate piece 20, col 5 lines 5-15), where the two tool parts are

arranged side by side at the gripping part (e.g., transition portion 21 – end portion 15 – pin 23 and transition portion 21 – end portion 15 – peak 24 with respect to the intermediate piece 20 in Fig. 5); but does not disclose a holder for the manipulators. However, Voroba discloses a holder (battery dispensing and removal apparatus, for hearing aid, see Fig. 1 and 6) with a number of pockets (e.g., battery dispensing station 70, col 5 lines 15-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a holder to accommodate small parts of a hearing aid. As a holder will be beneficial to store and dispense filter manipulators that are usually tiny and thus hard to handle, one would have been motivated to add Voroba's holder to the system disclosed by Gunnensen et al to make it easier to use.

Claim 16: Gunnensen et al and Voroba disclose a hearing aid system as in Claim 15; but Gunnensen et al does not disclose a snap lock mechanism between the holder and the filter manipulator. However, Voroba discloses a snap lock mechanism for releasable engagement (e.g., holding pad 75 and support rail 59, col 5 lines 30-55, Fig. 14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a snap lock mechanism. As the snap lock mechanism will hold a specific hearing aid part in place, one would have been motivated to add Voroba's snap lock mechanism to the system disclosed by Gunnensen et al to secure the filter manipulator.

Allowable Subject Matter

19. The following is a statement of reasons for the indication of allowable subject matter:

20. Claim 7 is objected to as being dependent upon a rejected base claim (Claim 1), but would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 7 recites that “the blade parts are arranged to extend along the surface of the edge portion of the gripping part but distanced from said edge portion” (page 10 lines 6-16 and Fig. 5-25 and 26). The prior art of record does not teach or render obvious the limitations as recited, specific to the explicitly detailed structural description (see underlined claim recitation) about the blade parts.

Claim 9-10 are objected to as being dependent upon a rejected base claim (Claim 8), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The primary reason for the allowance of the claims is the inclusion of the limitation “inwardly extending flange” (page 9 lines 15-30). The prior art of record does not teach or render obvious the limitation as recited. In order to assure allowability, the limitation “inwardly extending flange” shall not be recited in alternative form (- or -, in Claim 8).

21. Claim 17-18 are objected to as being dependent upon a rejected base claim (Claim 15), but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims. The primary reason for the allowance of the claims is the inclusion of the limitation "U-shape cut out" (page 7 lines 5-9). The prior art of record does not teach or render obvious the limitation as recited. Voroba disclose U-shaped cut outs in the holder and Gunnensen et al discloses a filter manipulator, but it is not obvious to conceive that a U-shaped cut out is necessary to a filter manipulator.

22. Claim 19 is objected to as being dependent upon a rejected base claim (Claim 15), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The primary reason for the allowance of the claim is the inclusion of the limitation "shaped in asymmetric fashion" (page 7 lines 15-19). The prior art of record does not teach or render obvious the limitation as recited.

23. Claim 20 is objected to as being dependent upon a rejected base claim (Claim 15), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The primary reason for the allowance of the claim is the inclusion of the limitation "material parts or shoulders" (page 7 lines 21-26) that narrowly surrounds the second tool part to prevent insertion once a used filter is held. The prior art of record does not teach or render obvious the limitation as recited.

24. Claim 21 is objected to as being dependent upon a rejected base claim (Claim 15), but would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and rewritten in independent form including all of the limitations of the base claim and any intervening claims. The primary reason for the allowance of the claim is the inclusion of the limitation on the "U-shaped cut-out" (page 7 lines 28-32) that assures the asymmetric relationship between the manipulator and the pocket. The prior art of record does not teach or render obvious the limitations as recited.

25. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Bauman (5,982,908) discloses an ear wax collection device for a hearing aid; Bisgaard et al. (4,984,277) discloses a protection element for a hearing aid; Carbe et al. (5,278,360) discloses a hearing aid wax guard with integral bridge; Leedom et al. (2002/0027996) discloses a disposable modular hearing aid; Mahoney et al. (6,205,227) discloses a peritympanic hearing instrument; Weiss et al. (4,870,689, 4,972,488) discloses an ear wax barrier for a hearing aid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Powen Ru whose telephone number is 571-270-1050. The examiner can normally be reached on Monday-Thursday 8am-3pm EST/EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Myhre can be reached on 571-270-1065. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PR
7/7/2006



James W. Myhre
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